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DEPARTMENT OF AGRICULTURE ADRIAN J. POLANSKY, SECRETARY

August 13, 2004

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: Docket No. 2004N-0264 / Regulatory Identification No. 0910-AF46

Dear FDA Docket Clerk:

I welcome the opportunity to comment on FDA's advanced notice of proposed rulemaking published in the July 14 Federal Register.

Beef production is extremely important to the Kansas economy and the financial well-being of Kansas ranchers. In 2002, Kansas ranked second among the states in cattle slaughtered and third in red meat production. That same year, producers reported cash receipts of \$4.8 billion, or 61.2 percent of all farm receipts.

The Kansas Department of Agriculture, much like USDA and FDA, has been diligent about taking action to prevent bovine spongiform encephalopathy. We immediately recognized the important role feed regulations play in preventing the spread of this disease, and we readily agreed to carry out feed mill inspections on behalf of FDA after new regulations were adopted in 1997. In 2001, the Kansas Legislature adopted FDA's feed regulations to allow state-level enforcement.

Our feed mill inspections focus on facility record keeping, measures to prevent commingling feed, and confirming that ingredients deemed prohibited for cattle feed are adequately marked with a cautionary statement. Laboratory staff used microscopy techniques to analyze feed until 2000, when we switched to PCR instruments to extract DNA from feed to test its source. Currently, we use test strips that allow us to detect the presence of prohibited materials more quickly than with PCR technology.

Fortunately, domestic demand for beef has not waned since BSE was diagnosed in a Washington state cow last December. Consumer confidence is very important and the regulations being considered by FDA could play a pivotal role in sustaining that confidence. We

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want consumers at home and abroad to be assured that American beef, and especially Kansas beef, is both safe and wholesome.

Throughout the advance notice of proposed rulemaking, FDA asks if sufficient scientific data are available to support its proposed regulation changes and other recommendations made by the International Review Team. I agree that competent, verifiable data are essential to justify FDA actions to change feed regulations. However, when incomplete or conflicting data are offered, I recommend that FDA consider how well the regulations address actual field practices and how they can reinforce domestic and international consumer confidence.

Specifically, absent other actions by FDA, including an outright ban on specified risk materials in all animal feed, I agree with FDA's proposal to remove the exemptions for blood and blood products, plate waste and poultry litter. Also, if SRMs are not prohibited from all animal feed, I would support requiring dedicated equipment, production lines and facilities to prevent inadvertent feed contamination.

The International Review Team made several more recommendations that warrant further study. I recommend that FDA carefully assess all of their recommendations, as well as the use of SRMs and banning all mammalian and avian meat and bone meal in ruminant feed. Again, I would emphasize that any proposed regulations take into account actual field practices. They need to be sufficiently clear that inspectors are able to effectively enforce them.

Thank you for the opportunity to comment on this important issue.

Respectfully yours,

Adrian J. Polansky

Kansas Secretary of Agriculture